SENATE BILL No. 366

Introduced by Senator Aanestad

February 20, 2007

An act to amend and repeal Section 1271 of the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

SB 366, as introduced, Aanestad. Clinical laboratories: personnel.

Existing law generally establishes a maximum workload for the examination of gynecologic slides by a cytotechnologist when performing a manual review of slides. However, existing law, until January 1, 2008, provides that specified federal workload requirements shall apply when reviewing those slides using automated or semiautomated screening devices approved by the Federal Food and Drug Administration and requires the technical supervisor of an individual who performs primary screening to establish the maximum workload for that individual in accordance with specified federal criteria. Existing law also provides, until January 1, 2008, that where cytotechnologists are represented by a labor organization, these maximum workload requirements shall be contained in a collective bargaining agreement or memorandum of understanding.

This bill would continue the operation of these provisions indefinitely.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 1271 of the Business and Professions Code, as amended by Section 1 of Chapter 735 of the Statutes of 2004, is amended to read:

1271. (a) A cytotechnologist shall not examine more than 80 gynecologic slides in a 24-hour period when performing a manual review of slides.

(b) The maximum workload limit in subdivision (a) is the maximum number of gynecologic slides that a cytotechnologist shall examine in a 24-hour period without regard to the number of clinical laboratories or other persons for which the work is performed. Cytotechnologists, who examine both gynecologic and nongynecologic slides, shall do so on a pro rata basis so that the maximum workload limit in subdivision (a) is not exceeded, and so that the number of gynecologic slides examined is reduced proportionally if both gynecologic and nongynecologic slides are examined in a 24-hour period.

(c) The maximum workload limit in subdivision (a) is for a cytotechnologist who has no duties other than the evaluation of gynecological slides. Cytotechnologists who have other duties, including, but not limited to, the preparation and staining of cytologic slides, shall decrease on a pro rata basis the number of slides examined.

(d) All cytologic slides shall be examined in a clinical laboratory that has been licensed by the department, or in a municipal or county laboratory established under Section 101150 of the Health and Safety Code. All slides examined under the name of a clinical laboratory shall be examined on the premises of that laboratory.

(e) Each clinical laboratory shall maintain records of the number of cases and slides for gynecologic and nongynecologic samples examined on a monthly and annual basis.

(f) Each cytotechnologist shall maintain current records in a form prescribed by the department of hours worked and the names and addresses of the clinical laboratories or other persons for whom slides are examined.

(g) Each clinical laboratory shall retain all cytology slides and cell blocks examined for a minimum of five years and all cytology reports for a minimum of 10 years.

(h) The presence of any factor that would prohibit the proper examination of a cytologic slide, including, but not limited to, damaged slides or inadequate specimens, as determined by the director of the laboratory, shall result in the issuance of a statement of inadequacy to the referring physician and no report of cytologic findings shall be issued on that slide.

(i) Each clinical laboratory shall maintain records of the number of cases and slides for gynecologic and nongynecologic slides each cytotechnologist in the laboratory reads each 24-hour period, the number of hours devoted during each 24-hour period to screening cytology slides by each individual, and shall determine weekly and cumulatively the frequency of abnormal slides found by each cytotechnologist employed.

(j) Ten percent of the negative or normal slides examined by each cytotechnologist employed by a clinical laboratory shall be rescreened at least weekly by a cytopathologist or supervising cytotechnologist other than the original examiner.

(k) When reviewing gynecologic slides using automated or semiautomated screening devices approved by the federal Food and Drug Administration, a laboratory shall follow the workload requirements established by Section 493.1274 of Title 42 of the Code of Federal Regulations.

(1) Any slide reviewed using automated or semiautomated screening devices approved by the federal Food and Drug Administration that requires full manual review shall be counted against the applicable limits established in subdivision (a) and this subdivision.

(2) On or before June 30, 2007, the State Department of Health Services shall review published evidence-based peer review journal articles that review the performance of both automated and semiautomated screening devices, subsequent to the approval of the device by the federal Food and Drug Administration, and shall determine whether increasing the number of slides reviewed on a daily basis increases the rate of error. If the department determines that the volume of screening on these devices increases the rate of error, the department may issue new regulations in that regard that are consistent with Section 493.1274 of Title 42 of the Code of Federal Regulations.

(*l*) The technical supervisor of an individual who performs primary screening shall establish the maximum workload limit for the individual, based on the individual's performance, in accordance with the criteria set forth in Section 493.1274(d)(1) of Title 42 of the Code of Federal Regulations.

(m) Where cytotechnologists are represented by a labor organization, the maximum workload limitations otherwise established pursuant to this section shall be contained in a collective

bargaining agreement or memorandum of understanding negotiated between the employer and the labor organization.

~~(n) This section shall remain in effect only until January 1, 2008, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2008, deletes or extends that date.~~

SEC. 2. Section 1271 of the Business and Professions Code, as added by Section 2 of Chapter 735 of the Statutes of 2004, is repealed.

~~1271. (a) A cytotechnologist shall not examine more than 80 gynecologic slides in a 24-hour period.~~

~~(b) The maximum workload limit in subdivision (a) is the maximum number of gynecologic slides that a cytotechnologist shall examine in a 24-hour period without regard to the number of clinical laboratories or other persons for which the work is performed. Cytotechnologists who examine both gynecologic and nongynecologic slides shall do so on a pro rata basis so that the maximum workload limit in subdivision (a) is not exceeded, and so that the number of gynecologic slides examined is reduced proportionally if both gynecologic and nongynecologic slides are examined in a 24-hour period.~~

~~(c) The maximum workload limit in subdivision (a) is for a cytotechnologist who has no duties other than the evaluation of gynecological slides. Cytotechnologists who have other duties, including, but not limited to, the preparation and staining of cytologic slides, shall decrease on a pro rata basis the number of slides examined.~~

~~(d) All cytologic slides shall be examined in a clinical laboratory that has been licensed by the department, or in a municipal or county laboratory established under Section 101150 of the Health and Safety Code. All slides examined under the name of a clinical laboratory shall be examined on the premises of that laboratory.~~

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~~(f) Each cytotechnologist shall maintain current records in a form prescribed by the department of hours worked and the names and addresses of the clinical laboratories or other persons for whom slides are examined.~~

~~(g) Each clinical laboratory shall retain all cytology slides and cell blocks examined for a minimum of five years and all cytology reports for a minimum of 10 years.~~

~~(h) The presence of any factor that would prohibit the proper examination of a cytologic slide, including, but not limited to, damaged slides or inadequate specimens, as determined by the director of the laboratory, shall result in the issuance of a statement of inadequacy to the referring physician and no report of cytologic findings shall be issued on that slide.~~

~~(i) Each clinical laboratory shall maintain records of the number of cases and slides for gynecologic and nongynecologic slides each cytotechnologist in the laboratory reads each 24-hour period, the number of hours devoted during each 24-hour period to screening cytology slides by each individual, and shall determine weekly and cumulatively the frequency of abnormal slides found by each cytotechnologist employed.~~

~~(j) Ten percent of the negative or normal slides examined by each cytotechnologist employed by a clinical laboratory shall be rescreened at least weekly by a cytopathologist or supervising cytotechnologist other than the original examiner.~~

~~(k) This section shall become operative on January 1, 2008.~~

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